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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,717	01/08/2004	Simon Jon Dunmore	00537-110003	6273

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,717	DUNMORE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/07 has been entered.

2. Applicant's arguments filed 9/26/07 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The disclosure is objected to because of the following informalities:

Table II on page 17 of the specification lists SSTR-5 values in both columns, yet have a third column related to SSTR-2/SSTR-5" ratios.

Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application is apparent for the new recitation of "and to exhibit a Ki value to said somatostatin type-5 receptor at least ***2.5 times*** greater then a Ki value of said compound to a somatostatin type-2 receptor" in base claim 1. In contrast, page 7 of the specification alternatively contemplates preferred SSTR-5 agonists as being "at least 3 times as selective for SSTR-5 as for SSTR-2". Therefore, the recitation of "at least 2.5 times..." is broader than that contemplated within the instant specification; thereby, constituting new matter.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The omitted elements are: the binding step for the SSTR-2 receptor, because otherwise, no comparison of "at least 2.5 times..." with the SSTR-5 receptor can be determined.

7. Claims 1-3, 5, 7-11, 13, 15-16 & 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. (IDS Ref #I) or Moore et al. (IDS Ref #J), in view of Yamada et al. (IDS Ref #O), for the reasons made of record in Paper NOs: 20070110 & 20070720, and as follows.

Applicants argue on pages 5-8 of the response that "neither Moore nor Inoue teach or suggest that of the five SST receptors, activity of the SSTR5 sub-type receptor is responsible for the reduction in amylin secretion", and that "no teachings in Yamada, Inoue and/or Moore... would have led the skilled artisan to expect that an SSTR5 selective agonist would decrease amylin secretion any better than an agonist to SSTR1, SSTR2, SSTR3 and/or SSTR4". In contrast to Applicants' assertions, the pending rejection is based on the combined teachings of all the cited references, not just Moore or Inoue, in which Applicants are reading limitations into their claims which are not present. Second, in contrast to Applicants' assertions, Yamada specifically teach that the rank potency of somatostatin analogs to bind to human SSTR-5 are: somatostatin-28>somatostatin-14 >>RC-160>SMS201-995, based on competition studies. Accordingly, the full length somatostatin polypeptides used in the methods of Moore and Inoue would further reasonably bind even better because somatostatin itself, along with the smaller molecule somatostain-28, inhibits amylin release from amylin-secreting cells, as already made of record. Therefore, absent evidence to the contrary, Moore's and Inoue's somatostatin, and Yamada's somatostain-28, reasonably meet the current limitations of the claims.

In summary, Inoue et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting rodent pancreas cells (i.e., as it relates to claims 1-2, 10-11, 13,

15-16 & 18), which therefore reasonably provides evidence that somatostatin inherently binds to SSTR-5 better than SSTR-2; absent evidence to the contrary. The pancreatic cells are incubated with the amylin release stimulators, glucose or arginine, under conditions in which amylin secretion is induced, followed by addition of somatostatin, in which amylin secretion is then inhibited by 40-70% (pg. 251, Abstract and pg. 252, Figure 1A and Table 1). However, Inoue et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Moore et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting pancreas cells (i.e., HIT T15 β-islet cells; as it relates to claims 1-2 & 10-11). The pancreatic cells are incubated with the amylin release stimulators, glucose plus arginine, under conditions in which amylin secretion is induced, followed by addition of somatostatin, in which amylin secretion is subsequently inhibited by 40% (pgs. 5-6 and Figure 5B,) which therefore reasonably provides evidence that somatostatin inherently binds to SSTR-5 better than SSTR-2; absent evidence to the contrary. However, Moore et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Yamada et al. teach a method for obtaining preparations containing SSTR-5 that are used to determine the ability of compounds to bind to SSTR-5 (i.e., the first step of the method of claim 1). The rank potency of somatostatin analogs are: somatostatin-28>somatostatin-14 >>RC-160>SMS201-995 for human SSTR-5, based on competition studies (pg. 844, Abstract), and therefore, provides evidence that somatostatin-28 is better than somatostatin-14 for binding to the SSTR-5 type receptor. Yamada further teach that after obtaining a preparation of cell membranes (i.e., as it relates to claims 1 & 3), which contains SSTR-5 (i.e., COS1 cells expressing SSTR-5; as it relates to the equivalent transfected cells of claims 5 & 7), incubation

with a detectably labeled ligand (i.e., [^{125}I-Tyr^{11}]- somatostatin-14; as it relates to claims 8-9) in the presence of the compounds somatostatin-14, somatostatin-28, SMS201-995 and RC-160 compete against labeled somatostatin-14 for binding to SSTR-5. However, Yamada do not teach obtaining amylin-secreting pancreatic cells in their method (i.e., the second step of claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use the method of Yamada et al. for determining binding compounds for SSTR-5, followed by evaluation of the biological effects of SSTR-5 compounds using the method of Moore or Inoue to inhibit amylin secretion in pancreatic cells, because agonists have similar functional activities as native ligands by definition, and because Yamada specifically suggest that use of somatostatin subtypes (e.g., SSTR-5 agonists, such a somatostatin-28) should reveal the molecular basis for somatostatin function, which includes exocrine and endocrine function (i.e., amylin inhibition) in the pancreas, pituitary and GI tract (see pgs. 851 and 845).

8. Claims 1-11, 13, 15-16 & 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. or Moore et al., in view of Yamada et al., as applied to claims 1-3, 5, 7-11, 13, 15-16 & 18 above, and further in view of Hoyer et al. (IDS Ref #H), for the reasons made of record in Paper NOs: 20070110 & 20070720, and as follows.

The rejection is maintained for similar reasons discussed above in *pp* #7. Therefore, Applicants' arguments on pages 8-9 of the response are also not persuasive for the reasons made of record.

In summary, Inoue et al., Moore et al. and Yamada et al. are as described above. However, none of these three references teach that rodent olfactory bulb contain SSTR-5 receptors.

Hoyer et al. teach numerous sources for cell preparations that contain SSTR-5 in Table 3 (pg. 447) that includes rat olfactory bulb (as it relates to claims 4 & 6), as well as CHO-K1 cells

transfected with SSTR-5 (pgs. 444-445 and Fig. 2; as it relates to claims 5 & 7). However, Hoyer do not specifically teach subsequent inhibition of amylin secretion in pancreatic cells, even though they do disclose that somatostatin inhibits the pancreatic-associated hormones insulin and glucagon with different pharmaceutical profiles (pg. 441, 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use Hoyer's cell preparations (i.e., rat olfactory bulb and CHO-K1/SSTR-5 cells; as it relates to claims 4-7), or Hoyer's somatostatin agonists (pg. 443, Table 2) in the method of Yamada as described above, because different tissues express different levels of SSTR-5 and thus provides an additional source of cell/membrane preparations for carrying out Yamada's method using competing SSTR-5 binding compounds when combined with the methods of Inoue or Moore for inhibiting amylin secretion, as discussed above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
December 21, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER